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Dated: June 30, 2009

Signature: / Thomas W. Humphrey /  
(Thomas W. Humphrey)

Docket No.: LF 227  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:  
Michael R. Hynes

Application No.: 10/811,258

Confirmation No.: 1651

Filed: March 26, 2004

Art Unit: 3767

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For: Calibrated Pushrod for Injection Volume  
Control in Prefilled Syringes

Examiner: Elizabeth Rose  
Moulton

### **REPLY BRIEF**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Madam:

Pursuant to §41.41, this reply brief is being filed in response to the  
Examiner's Answer that was mailed on May 12, 2009.

This reply brief contains, under the appropriate headings and in the order  
indicated, the following items as required by 37 C.F.R. § 41.41:

- I. Table of Contents
- II. Table of Authorities
- III. Statement of additional facts
- IV. Argument

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## **II. TABLE OF AUTHORITIES**

No court or administrative decisions, statutes, or other authorities are cited in this brief.

### **III. STATEMENT OF FACTS**

With regard to the present application, the Examiner's answer asserts that "there is no special definition of a prefilled syringe in the specification or in the art, asserting that "any syringe which contains medication for expulsion is prefilled." The Examiner is incorrect, and is ignoring that the present application is by its title directed to "prefilled" syringes and that the specification at page 4 lines 17 – 24 specifically refers to "[p]refilled syringes [which] are available containing a variety of medical fluids", in "sizes relating somewhat to typical and/or average dosages". "Prefilled" clearly has been used in the specification in reference to syringes which are sold with medical fluids in them in typical dosage sizes – it does not refer to a syringe sold empty and then filled with a patient-specific amount of medical fluid.

With regard to the Travelent patent, the Examiner incorrectly asserts that Travelent "expressly discloses that the plunger is calibrated to the volume of the syringe: see Col. 3 line 57 – Col. 4 line 14". This misstates the quoted section of the Travelent, which states only that the pitch of the threads on the plunger of the Travelent syringe may be adjusted based on the length of the plunger. This section of Travelent does not address or relate to the issue at hand, which is whether the "0" on the plunger of the syringe is or is not in alignment with the syringe body so that the scale is meaningful.

With respect to Blackman, the Examiner incorrectly asserts that Blackman shows a “scale” for the reason that col. 4, line 64 of Blackman states that the syringe has grooves that “correspond to a predetermined volume”. The Examiner relies on an Internet dictionary for a definition of “scale”, ignoring that the present application uses the word “scale” to refer to the numbers shown in Fig. 2, which are adjacent to the thread lines 36 (see Fig. 2 and page 5, line 20). The application further notes that the scale 32 “reads from 0 to 9 mL” (page 6 line 3). Thus “scale” is defined in the application as an annotated volume indication – it is not used for mere grooves or thread lines and is not satisfied by mere grooves or thread lines.

Also regarding Blackman, the Examiner incorrectly asserts that the detent 36 is a “stop”; there is no disclosure in Blackman that the detent 36 serves to stop the plunger as opposed to simply providing a feedback click. In contrast, in the present application the “stop” stops the plunger, e.g. at page 6 line 12-14: “pushrod 14 and plunger 20 are prevented from traveling any further and stop when stop 30 contacts flange 44 of barrel 34, thereby controlling the injection volume” (emphasis added). The Examiner has failed to show how the Blackman detent stops the plunger or prevents its travel – it is not a “stop”.

#### **IV. ARGUMENT**

For the reasons noted above, Applicant re-asserts that the presently claimed invention clearly distinguishes the Travelent and Blackman references relied upon by the Examiner, due to the failure to show a “prefilled” syringe with a shaft with a “scale” that corresponds to a “known” amount prefilled in the syringe, and a “stop” that is set according to the scale.

For the reasons given in this reply brief and in the appeal brief, reversal of the examiner’s rejection is requested.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23-3000, under Order No. LF 227 from which the undersigned is authorized to draw.

Dated: June 30, 2009

Respectfully submitted,

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